REMARKS

Favorable reconsideration, reexamination, and allowance of the present patent application are respectfully requested in view of the foregoing amendments and the following remarks. Claim 6 has been cancelled without prejudice, and as such, no new matter has been added by the above amendment.

Rejection under 35 U.S.C. § 103(a)

In the Office Action, beginning at page 3, Claims 1, 2 and 5-7 were rejected under 35 U.S.C. § 103(a), as reciting subject matters that allegedly are obvious, and therefore allegedly unpatentable, over the disclosure of Kunio Tsuji (JP 8-27008), hereinafter "Tsuji". Applicant respectfully requests reconsideration of this rejection for the following reasons.

Applicant disagrees with the assessment of Tsuji presented in the Office Action, and respectfully asserts that this assessment is in error. Specifically, Tsuji do not teach or render obvious nucleoside salts. Also, the Office Action asserts that Tsuji presents an example with inosine as the nucleoside and an arginine salt as the salt (Page 4, lines 3-4); however, such assertion is in error for the following reasons.

Tsuji distinguish carefully, at paragraphs [0017]-[0018], between a nucleoside (such as inosine), a nucleotide (such as 5'-inosinic acid or inosine 5'-phosphate) and a nucleotide salt (such as disodium-5'-inosinate), and never disclose any nucleoside salts. Applicants provide a translation for the Examiner's convenience of the pertinant material sections of this reference. Inosine is not a typical acid, such as an inorganic acid, e.g., HCl, H_2SO_4, H_3PO_4 or an organic acid, e.g., a carboxylic acid, and it can be assumed that inosine reacts with a base such as arginine at its phenolic hydroxyl group.

Therefore, the inventive inosine L-arginine salt is a novel compound, and is definitely not rendered obvious by the disclosure of Tsuji.

For at least the foregoing reasons, Applicant respectfully submits that the subject

matters of Claims 1, 2 and 5-7, each taken as a whole, would not have been obvious to one of ordinary skill in the art at the time of Applicant's invention, are therefore not unpatentable under 35 U.S.C. § 103(a), and therefore respectfully requests withdrawal of the rejection thereof under 35 U.S.C. § 103(a).

In the Office Action, beginning at page 4, Claims 3, 4 and 14 were rejected under 35 U.S.C. § 103(a), as reciting subject matters that allegedly are obvious, and therefore allegedly unpatentable, over the disclosure of Kunio Tsuji (JP 8-27008), hereinafter "Tsuji". Applicant respectfully requests reconsideration of this rejection for the following reasons.

The Office Action alleges that Tsuji teaches the process of making nucleoside salts generally, including dissolving the nucleoside and the amino acid in water and that the process of making said salts as described by Tsuji is a just standard acid/base reaction and would easily fall within the purview of one of ordinary skill, including the addition of anhydrous ethanol, which is a well known and widely available solvent used in such reactions. Applicant respectfully disagrees with this assessment. Firstly, please note that Tsuji never teach the process of making any nucleoside salts. Furthermore, the inventive process of making inosine-L-arginine salt as set forth in the instant application can never be said to be 'just a standard acid/base reaction,' because said inosine is not a typical acid, as explained above. Please refer to the attached translation of the pertinant material sections of Tsuji for support of the above statements

For at least the foregoing reasons, Applicant respectfully submits that the subject matters of Claims 3, 4 and 14, each taken as a whole, would not have been obvious to one of ordinary skill in the art at the time of Applicant's invention, are therefore not unpatentable under 35 U.S.C. § 103(a), and therefore respectfully requests withdrawal of the rejection thereof under 35 U.S.C. § 103(a).

Conclusion

For at least the foregoing reasons, Applicant respectfully submits that the present patent application is in condition for allowance. An early indication of the allowability of the present patent application is therefore respectfully solicited.

If Examiner Johnsen believes that a telephone conference with the undersigned would expedite passage of the present patent application to issue, he is invited to call on the number below.

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and the undersigned respectfully requests that she be contacted immediately.

Respectfully submitted,

By: _____

Shelly Guest Cermak
Registration No. 39,571

U.S. P.T.O. Customer No. 38108
Cermak & Kenealy, LLP
515 E. Braddock Road, Suite B
Alexandria, VA 22314
703.778.6608

Date: May 26, 2005

CLAIMS

[Claim(s)]

[Claim 1] The antibody forming cell inhibitor which consists of one sort chosen from a nucleoside, a nucleotide, and a nucleotide salt, or two sorts or more.

[Claim 2] The antibody forming cell inhibitor according to claim 1 characterized by said nucleoside being inosine.

[Claim 3] The antibody forming cell inhibitor according to claim 1 characterized by said nucleotide being inosinic acid.

[Claim 4] The allergic disease remedy which contains the antibody forming cell inhibitor in any 1 term of claims 1-3 as an active principle.

[Claim 5] The allergic disease remedy according to claim 4 characterized by being skin external preparations.

[Claim 6] The autoimmune disease remedy which contains the antibody forming cell inhibitor in any 1 term of claims 1-3 as an active principle.

DETAILED DESCRIPTION

[Detailed Description of the Invention]

[0001]

[Industrial Application] This invention relates to an antibody forming cell inhibitor, an allergic disease remedy and an autoimmune disease remedy. Specifically it relates to an antibody forming cell inhibitor which are chosen from nucleoside, a nucleotide, and a nucleotide salt, and an allergic disease remedy and an autoimmune disease remedy which contains as an active component the antibody forming cell inhibitor.

[0002]

[Description of the Prior Art] In recent years, the disease person of autoimmune diseases such as systemic lupus erythematosus, a periarteritis nodosa, a scleroderma, dermatomyositis, and chronic articular rheumatism, or allergic diseases such as pollinosis, hay fever, atopic dermatitis, and delayed type contact dermatitis, is increasing rapidly with change of the life style centering on eating habits. Especially about pollinosis, the number of patients is increasing so that it is believed one of three persons has fallen ill. Moreover, also about the vegetation leading to pollinosis, it contains not only a spring Japan cedar, but also kaede, a Japanese oak, a ragweed, and a tall goldenrod, and others. Therefore a season of pollinosis has also come to cover all year round.

[0003] It is supposed that the superfluous correspondence in the bodies, such as an antibody forming cell, causes these allergic diseases and autoimmune diseases. For example, existence of variegated autoantibody and a self-antigen sensitized lymphocyte is found in the autoimmune disease. Some experimental data shows the reaction of autoantibody independence, a complement dependency, phagocyte antibody nature, and a killer cell dependency causes the organization failure. Moreover, an allergic disease is also an excessive self-defense reaction by the side of the living body to an external antigen, and it is supposed that superfluous correspondence of an antibody forming cell etc. is the cause.

[0004] Administration of an antihistamine, a steroid, etc. has been carried out to the therapy of such an allergic disease and an autoimmune disease in symptomatic therapy from before. However, even if it used these drugs, sufficient effectiveness was not acquired, but since [that a side effect is strong] a sake and long-term repetitive administration were not able to be carried out, the use had a big limit. Then, as a means of a fundamental therapy against an allergic disease or an autoimmune disease, drugs which control growth of an antibody forming cell and development of the therapy approach using the drugs,

for example those which control the superfluous correspondence on the side of a living body, have been desired strongly

[0005] Moreover, it is also possible to prevent the onset of disease whose onsets is predicted, such as pollinosis, by controling superfluous correspondence of a living body, and development of the effective prophylactic-treatment means for it has been also desired.

[0006] It is not known that a nucleoside, a nucleotide and a nucleotide salt etc. will control growth of an antibody forming cell, and will, on the other hand, control a living body's superfluous correspondence reaction, and it does not have the report which used these for the prophylactic treatment and therapy of an allergic disease and an autoimmune disease, either.

[0007]

[Problem(s) to be Solved by the Invention] This invention is accomplished from the above view. The problem to be solved by the invention is to provide a drug which controls the superfluous correspondence reaction of the living body which causes allergic disease and autoimmune disease, and especially to provide a drug which inhibits growth of an antibody forming cell. Furthermore, the problem to be solved by the invention is to provide a highly safe and sufficiently

effective allergic disease remedy and autoimmune disease remedy by blending this antibody sexuparaous cell inhibitor.

[0008]

[Means for Solving the Problem] The inventors completed this invention by asking for a material which controls a superfluous correspondence reaction, with repeating screening for antibody forming cell depressant action against an index for various materials. As the result, this invention was completed by finding an operation of a nucleoside, a nucleotide, and a nucleotide salt that they control growth of an antibody forming cell and a superfluous correspondence reaction.

[0009] That is, this invention is an antibody forming cell inhibitor which consists of one sort chosen from a nucleoside, a nucleotide and a nucleotide salt, or two sorts or more, and the allergic disease remedy and autoimmune disease remedy which contain the inhibitor as an active agent.

[0010] Here, the "therapy" in an allergic disease remedy and an autoimmune disease remedy in this specification is used as a concept including the so-called prophylactic treatment which prevents the onset of a symptom in addition to a therapy for controlling or reducing a symptom.

[0011] Hereafter, this invention is explained to a detail.

[0012] <1>The antibody forming cell inhibitor of this invention

The antibody forming cell inhibitor of this invention consists of one sort chosen from a nucleoside, a nucleotide and a nucleotide salt, or two sorts or more.

[0013] Here, a nucleoside is the nucleic-acid analog which is combined nucleobase and monosaccharide, and, specifically, purine nucleosides such as inosine, an adenosine, and a guanosine, pyrimidine nucleosides such as a cytidine, thymidine, and a uridine, can be illustrated. Furthermore, it is possible to also use deformation nucleosides, such as a pseudouridine and a tubercidin, as an antibody forming cell inhibitor of this invention besides this.

[0014] Here, a nucleotide it ester compound between one or more of the hydroxyl group of the sugar chain of the above-mentioned nucleoside and the a phosphoric acid, and, specifically, includes inosinic acid, an adenylic acid, a guanylic acid, cytidylic acid, thymidylic acid, uridylic acid, etc.. Here, in a nucleoside, since the hydroxyl group by which phosphorylation is carried out can be positioned at 2' , 3 ' and 5', three kinds of isomers exist for the above-mentioned nucleotide. If inosinic acid is mentioned as an example, these will be three sorts of 2'-inosinic acid and 3 '- inosinic acid and 5'-inosinic acid.

[0015] There are nucleotides, such as a 1 phosphorylation object, a

diphosphoric acid ghost, and a triphosphoric acid ghost, among the nucleotides with the number of the phosphoric acids which some which the phosphoric acid combined with the phosphoric acid which carried out [above-mentioned] the ester bond further have, and were combined with the nucleoside. For example, although the above-mentioned inosinic acid is inosine 1 phosphoric acid, there is inosine-5 '-2 phosphoric-acid and inosine -5'-3 phosphoric acid which the phosphoric acid combined with the 1 inosine-5'-1 phosphoric acid (5'-inosinic acid) of the inosinic acid further.

[0016] Furthermore, although it is also possible to use the salt of the above-mentioned nucleotide for the antibody forming cell inhibitor of this invention, if it is a physiologically permissible salt as such a salt, there will be especially no limitation as to the salt. It includes a salt of a nucleotide and alkali metal, such as sodium, a potassium and a lithium, a salt with alkaline earth metals, such as magnesium and calcium, a salt with ammonium, such as ammonium, triethyl ammonium, and triethanol ammonium, and a salt with basic amino acid, such as an arginine and a lysine etc..

[0017] Although the antibody forming cell inhibitor of this invention is constituted using the above-mentioned nucleoside, nucleotide, and nucleotide salt, in this

invention, these one sort may be used independently and you may use combining two or more sorts. Moreover, in this invention, inosine, inosinic acid, and inosinic acid salt etc. is preferably used among these compounds. In addition, these nucleosides, nucleotides and nucleotide salts exit as a nucleic acid group materials in the living body and each of these compounds is on market, acquisition is easy.

[0018] furthermore, the fact that these nucleosides, nucleotide, and nucleotide salts exits plentifully by the matter in the living body as a nucleic acid group material shows that they are highly safe.